

inventors Kazuhiko Amano, Kazuo **Uebaba**, and Hitoshi Ishiyama. Applicants hereby state through their undersigned attorney that Kazuo **Kodama** and Kazuo **Uebaba** are the same person, and Amano et al. (5,730,137) and the present application have the same inventive entities. Thus, Amano et al. (5,730,137) cannot form the basis of rejection under 35 U.S.C. 102(e)/ 103(a), and it is respectfully requested that the rejections of Claims 13, 14, 16, 17, 19, 21-24, and 25 be withdrawn. Further it is requested that the objections to Claims 15, 18 and 20 as being dependent on Amano-rejected base claims be withdrawn.

Claim 19 was rejected under 35 U.S.C. 112, second paragraph as being indefinite. This claim has been amended to remove the redundant language pointed out by the Examiner and to further clarify the claim. The Examiner's careful review is appreciated.

Claims 1, 4 and 10 were rejected under 35 U.S.C. 102 (b) as being anticipated by Cosgrove Jr. et al. Claim 1 has been cancelled. Claim 10 has been amended to depend on Claim 9, which has been written in independent form. Claim 9 in independent form was indicated as allowable by the Examiner, and now dependent Claim 10 should be allowable also.

Claim 4 (as well as Claim 3) has been written in independent form and has been further amended to recite a device comprising two administering means. A drug administered by one (first) administering means induces a state of arousal, and a drug administered by the other (second) administering means induces a state of sedation. Having the two administering means, the device of the present invention determines which administering means is to be used. Please see Fig. 112 of the present application and its related description beginning on page 126. It is respectfully submitted that such feature is neither shown nor suggested by the prior art, specifically Cosgrove with regard to Claim 4, and McNally, discussed hereinafter, with regard to Claims 3 and 4.

Claims 1-4, and 10 were rejected under 35 U.S.C. 102 (b) as being anticipated by McNally et al. Claims 1 (cancelled), 3, 4 and 10 are discussed in the foregoing paragraphs.

Claim 2, now written in independent form, was rejected by the Examiner as being anticipated by McNally et al. However, McNally et al. does not disclose or teach all of the elements of Claim 2. Specifically, there is nothing in McNally et al. that indicates the use of two different indicators of a physiological state in determining whether to issue a command to a drug administering means, the two indicators being "an indicator of a physiological state related to arousal or sedation" and "blood pressure". See, for example, "3. Control of administration of drug" on page 127 of the specification, for a description of how the two indicators are used in determining drug administration. In contrast to the present invention, McNally et al. performs such determination on the basis of a measured value of a patient's blood pressure only.

Claims 6-8, 11, and 12 were rejected 35 U.S.C. 103 (a) as being unpatentable over McNally et al. in view of Sherer. Claims 6-8 are dependent on Claim 3, discussed above, and are patentable for at least the same reasons. With regard to the rejection of Claim 11, now written in independent form, over McNally et al in view of Sherer, there is nothing in either of the prior art references that either teaches or suggests drug administration in synchronization with the blood pulse cycle. See the specification on page 136, line 24 et seq., for example. In Sherer, a patient's blood pressure and other parameters are constantly displayed or printed to monitor the patient's state during drug administration, but these parameters are not used in any way for determining the timing at which the drug is administered.

In view of the foregoing amendments and remarks, Applicant respectfully request favorable reconsideration of the present application.

Respectfully submitted,



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**Versions With Marking To Show Changes Made  
IN THE CLAIMS**

2. (Amended) A device for controlling a physiological state ~~according to claim 1, further comprising:~~

a measuring means for measuring an indicator of a physiological state related to arousal or sedation in a patient;

a means for measuring a patient's blood pressure;

an administering means for administering a drug to the patient; and

~~, and the drug administration control means issues a command to administer a drug~~ a drug administration control means for issuing a command to the administering means for drug administration when the indicator of the physiological state satisfies specific conditions and the blood pressure is a specific value.

3. (Amended) A device for controlling a physiological state ~~according to claim 1, further comprising:~~

a measuring means for measuring an indicator of a physiological state related to arousal or sedation in a patient;

a first recording means for storing an indicator of a desirable physiological state;

a first administering means for administering a drug to the patient which will elicit a state of arousal;

a second administering means for administering a drug to the patient which will elicit a state of sedation; and

~~-wherein the~~ a drug administration control means for comparing the indicator measured by the measuring means and the indicator stored in the first recording means, and for issuing a command, after a decision has been reached that the patient is in a state of sedation, ~~issues a~~ the command to administer a

drug to the patient which will elicit a state of arousal by the first administering means.

4. (Amended) A device for controlling a physiological state ~~according to claim 1,~~ further comprising:

a measuring means for measuring an indicator of a physiological state related to arousal or sedation in a patient;

a first recording means for storing an indicator of a desirable physiological state;

a first administering means for administering a drug to the patient which will elicit a state of arousal;

a second administering means for administering a drug to the patient which will elicit a state of sedation; and

~~wherein the~~ drug administration control means for comparing the indicator measured by the measuring means and the indicator stored in the first recording means, and for issuing a command, after a decision has been reached that the patient is in a state of arousal, ~~issues a~~ the command to administer a drug to the patient which will elicit a state of arousal by the second administering means.

5. (Amended) A device for controlling a physiological state according to claim ~~14,~~ wherein the drug administration control means issues a command to carry out drug administration only when a specified period of time has elapsed since the previous administration of the drug.

9. (Amended) A device for controlling a physiological state ~~according to claim 1,~~ further comprising:

a measuring means for measuring an indicator of a physiological state related to arousal or sedation in a patient;

an administering means for administering a drug to the patient;

a drug administration control means for issuing a command to the administering means for drug administration when the indicator of the physiological state satisfies specific conditions; and

a means for detecting the output of a drug administration command, determining from the point of this detection whether or not the indicator of physiological state has reached a state which does not satisfy the specified conditions, and providing notification when the indicator of the physiological state has reached a state which does not satisfy the specified conditions.

10. (Amended) A device for controlling a physiological state according to claim ~~19~~, wherein the administering means comprises an infuser of the drug.

11. (Amended) A device for controlling a physiological state ~~according to claim 1~~ further comprising:

a measuring means for measuring an indicator of a physiological state related to arousal or sedation in a patient;

an administering means for administering a drug to the patient;

a blood pulse detector for detecting a blood pulse cycle of blood sent from the patient's heart; and

a drug administration control means for issuing a command to the administering means for drug administration when the indicator of the physiological state satisfies specific conditions,

wherein the drug administration control means issues a command to administer a drug to the administering means during the time interval from one blood pulse beat to the next blood pulse beat in synchronization with the blood pulse cycle.

19. (Amended) A device for controlling a physiological state according to claim 16, wherein the control means selects a specified time period, and outputs a command to administer a drug when the indicator during the specified time period deviates a fixed amount above a moving average obtained in the past for the indicator ~~during the specified time period over a specified period of time.~~